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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/648,143	08/25/2000	Kevin D.J. Bowden	SW7255US	5341

22203 7590 04/24/2003

MARK KUSNER COMPANY LPA  
HIGHLAND PLACE SUITE 310  
6151 WILSON MILLS ROAD  
HIGHLAND HEIGHTS, OH 44143

EXAMINER

RADEMACHER, MARK A

ART UNIT

PAPER NUMBER

3761

DATE MAILED: 04/24/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/648,143	BOWDEN, KEVIN D.J.
	<b>Examiner</b>	<b>Art Unit</b>
	Mark Rademacher	3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
 THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-14 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 25 August 2000 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                               | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4 and 5</u> . | 6) <input type="checkbox"/> Other: _____.                                   |

## **DETAILED ACTION**

### *Drawings*

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “endotracheal tube” and the “flexible diaphragm, pneumatic pressure sensing valves, the rotation flow meter propellers and electrical gas flow sensors” must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.
2. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### *Specification*

3. The disclosure is objected to because of the following informalities: It is the examiner’s position that applicant has evoked sixth paragraph, means-plus-function language to define applicant’s invention. However, it is unclear what impliedly disclosed structure(s) are required to the means plus function recitation. Therefore the examiner requires the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element. Please note that the MPEP clearly states, “Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means-(or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second

paragraphs, the PTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)...”. (Also see **MPEP 2181** (Rev. 1, Feb.2000))

4. Appropriate correction is required.

### ***Claim Objections***

5. Claims 1-14 are objected to because of the following informalities: It is the Examiner’s position that the applicant has evoked sixth paragraph, means-plus-function language to define the applicant’s invention. Therefore the examiner has objected to the claims for the reasons set forth above in the objection to the specification.

6. Claim 3 is objected to because of the following informalities: in line 7, the applicant recites “the bag output valve”. It appears that the applicant is referring to the one way output valve” included in the flexible bag.

7. In depending claims 8-14, the applicant recites a preamble beginning “[a] bag-valve mask device...”. However, the preamble of the parent claims recite “[a] manually operated resuscitation device”. The preambles of the depending claims must be consistent with the parent claim(s).

8. For increased clarity the applicant is invited to use appropriate articles such as “a” and “the” when referring to features in the claims. For example, in claim 1, the applicant recites “between the gas inlet and patient airway engagement means”, which would be clearer if amended to either “a patient airway engagement means” or “the patient airway delivery means”; in claim 9, the applicant should recite “retainer means comprise a shoulder with a bulkhead abutting surface”, and so on.

9. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

11. The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

13. Claim 1 recites the limitation "the patient airway" in line 3. There is insufficient antecedent basis for this limitation in the claim. Depending claims 2-14 incorporate the antecedent deficiencies of claim 1.

***Claim Rejections - 35 USC § 102***

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

15. A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 1, 2 and 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by US patent no. 5,537,998 to *Bauman*.

17. *Bauman* discloses a manually operated resuscitation device in the form of a bag valve mask that includes a patient interface that has a gas inlet (opening 504) and a patient airway

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delivery means (bag 500), a one-way valve (flap or disc valve 516) downstream of the gas inlet, and a flow control means. See FIGS 6-12.

18. The flow control means automatically and variably limits the gas flow between a minimum flow rate and a maximum flow rate. Through movement of a plunger (532) which moves axially in bore (533) against spring (535), which urges the plunger (532) toward seat (519). As pressure increases the plunger is urged passed release holes (552) to release excess pressure and flow. See column 5, lines 19-55. Although the flow control means is described in terms of regulating pressure, the regulation of pressure inherently regulates flow.

19. The gas flow sensor may be considered the plunger surface perpendicular to the axis of movement of spring-loaded plunger (532). The orifice restriction means may be considered to comprise valve seat (plug 538) and the spring-loaded plunger (532). The spring (535) biases the plunger (532) away from the valve seat (538) and flow from the inlet biases the plunger toward the seat (538).

#### ***Claim Rejections - 35 USC § 103***

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

21. Claims 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Bauman* in view of US patent no. 3,009,459 to *Ruben*.

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22. *Bauman* expressly discloses all of the features recited in claim 3, including an exhaust port means (521), except for a one-way output valve in the flexible bag.

23. Note that *Bauman* discloses a mask (see dotted lines) and which is described further in parent applications/patents, which were incorporated into *Bauman* by reference. See column 3, lines 5-8, and, e.g., patent no. 4,812,713 also to *Bauman* therein incorporated by reference.

24. Resuscitation bags that include one-way output valves were well known at the time of invention however. For example, *Ruben* discloses a bag (1) having input and output valves (4 and 5).

25. At the time the invention was made one with ordinary skill in the art would have modified the bag disclosed by *Bauman* to include the one way output valve (5) disclosed by *Ruben* in order to prevent expansion of the bag from creating a negative pressure at the gas inlet (504) and ensuring that the bag is inflated only through input one way valve (4).

#### ***Allowable Subject Matter***

26. Claims 8-14 would be allowable if rewritten to overcome the objections and the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this office action and to include all of the limitations of the base claim and any intervening claims.

#### ***Additional Pertinent Prior Art***

27. The following is prior art made of record and not relied upon is considered pertinent to applicant's disclosure: US patent nos. 5537999 and 5651361 to *Dearman et al*, US patent nos.

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5,398,714 and 5,230,330 to *Price*, US patent no. 5,632,298 to *Artinian*, US patent no. 5,492,115 to *Abramov et al* and US patent no. 3,610,237 to *Barkalow*.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Rademacher whose telephone number is (703) 305-0842. The examiner can normally be reached on Monday through Friday, 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703) 308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

MAR  
April 11, 2003



GLENN K. DAWSON  
PRIMARY EXAMINER

***NOTICE – CHANGE OF ADDRESS FOR THE COMMISSIONER FOR PATENTS***

As of May 1st, 2003 the correspondence address for the Director of the USPTO and the Commissioner for Patents will be:

PO Box 1450  
Alexandria, VA 22313-1450

See, Federal Register, Vol. 68, No. 57, March 25, 2003.